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StarLink Corn Containment Program

**Data Requirement**

Not Applicable

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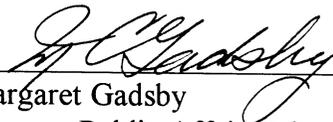


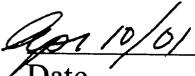
**STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS**

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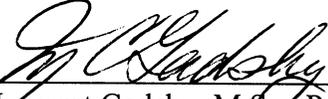
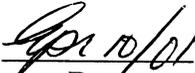
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**GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT**

The study presented herein is not subject to the 40 CFR 160 Good Laboratory Practice Standards.

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**StarLink Corn Containment Program**Executive Summary

Aventis CropScience, in cooperation with the USDA, has gone to great lengths to identify, locate and contain StarLink corn grain from the 2000 harvest. Over 99 percent of the corn grown from StarLink seed has been identified and is either being fed on farm or being transported (under controlled conditions) to USDA approved (non-food) destinations. StarLink corn that left the farm before the USDA sanctioned program was implemented, and corn that may contain Cry9C from other sources (such as corn grown in buffer fields and corn from varieties which may have contained Cry9C) has been identified at elevators and is also being shipped to approved sites. One can now conclude that the vast majority of corn containing Cry9C that was produced during the 2000 crop year has been contained and has been or will be directed to approved (non-food) destinations over the coming months.

The StarLink Enhanced Stewardship (SES) Program has brought all this corn under containment. A total of 26.07 M bushels of StarLink grain grown from seed and other sources is being fed to livestock on farm. In addition, 79.3 M bushels of Cry9C-containing corn is being directed to approved uses under supervised marketing. The SES Program is thus controlling the utilization of some 105.37 M bushels of corn grown during 2000 from all sources of Cry9C.

US grain handlers and elevator operators have implemented extensive testing to locate StarLink corn that may have entered commodity grain channels. It is now evident that a significant amount of the corn grown from StarLink seed during 1999 entered the grain handling system and that it is commingled with other corn at a ratio that may be as high as 1:100. Literally hundreds of barges and thousands of trucks and rail cars have been redirected as a result of containing extremely low levels of Cry9C-containing corn. To gain a sense of the magnitude for commingling if as much as 20 percent of the StarLink corn grown in 1999 entered commodity grain channels and was commingled at a ratio of 1:100, the result would be 750 million bushels of commingled corn. This represents roughly 7 percent of all corn in the commodity grain system.

To date, approximately 437 million bushels of Cry9C-containing commingled corn have been identified at elevators and is assumed to be from 1999 production. This corn, once identified, is being redirected to approved uses. 22% of it has already been utilized. Since 70 percent of all corn produced in the USA during 1999 had been processed (or consumed) prior to January 1, 2001, it is likely that the majority of 1999 StarLink corn has already been identified via testing at elevators.



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By September 2001, the vast majority of all corn grown from StarLink seed over all years (and any neighboring buffer corn or other varieties known to contain Cry9C) will have been directed to approved, non-food uses.

Action has been taken to reduce the probability of Cry9C appearing in the 2001 harvest. It should be noted, however, that it is likely that low levels of Cry9C-containing corn will persist. Continuing Cry9C sources include adventitious presence in seed, volunteer corn, and grain caught in combines, elevators or transportation vehicles. With the aggressive testing efforts now in place, where one kernel in 2400 is enough to reject a load, it is likely that any corn containing Cry9C will be identified and directed to non-food uses. As the amount of Cry9C-containing corn diminishes through the extensive efforts of the food chain, it also becomes more dispersed and more difficult to capture. In combination with very sensitive testing methods, detection of Cry9C-containing corn can be expected to continue for the foreseeable future.

## Introduction

In accordance with the agreement between Aventis CropScience and federal regulators, a StarLink Corn Containment Program has been implemented. This document summarizes the processes used and the conclusions that can be drawn from the containment efforts currently in place to deal with any Cry9C in the system, regardless of the source.

### 1999<sup>1</sup> StarLink Harvest

In 1999, StarLink corn was planted on ~250,000 acres in USA. This acreage is estimated to correspond to a theoretical harvest of [250,000 acres x 150 bushels/acre =] some 37.5 M bushels of StarLink grain. Retrospectively, it is difficult to determine the disposition of this grain however several facts can be considered.

- According to USDA statistics, about 70 percent of the corn produced during the 1999 harvest had been either consumed or processed as of January 1, 2001.
- Japan's Ministry of Agriculture, Forestry and Fisheries reported testing results for inbound corn grain shipments received between September and December 2000, which is likely to be almost exclusively composed of 1999 harvested grain. Of 19 shipments tested during this timeframe, 14 reportedly tested positive for Cry9C.
- Food recalls based upon the presence of Cry9C are believed to have originated primarily with 1999-derived commingled corn grain.
- As of March 20, 2001, Cry9C testing at elevators in the US has resulted in the identification of approximately 437 M bushels of commingled grain containing some level of Cry9C. It is most likely that this reflects commingling of the 1999 harvest since the implementation of the StarLink Enhanced Stewardship (SES) Program in late September 2000 restricted the movement of grain from the 2000 harvest.

Figure 1 indicates the capture of 1999-derived Cry9C-containing corn at various locations in the grain handling process.

The SES Program was not designed to capture 1999 StarLink grain. Less than 1% of the grain currently included in the on-farm SES Program has been identified as originating from 1999 StarLink production. Nonetheless, the testing regimes put in place at elevators and grain handling facilities as a part of the SES Program has captured a significant portion of the 1999 harvest that was not already directed to animal feed or industrial use.

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<sup>1</sup> StarLink corn was grown on ~10,000 acres in 1998 and would have yielded a theoretical harvest of 1.5 M bushels of grain. Records indicate that this grain was fed to cattle.

## 1999 StarLink Grain

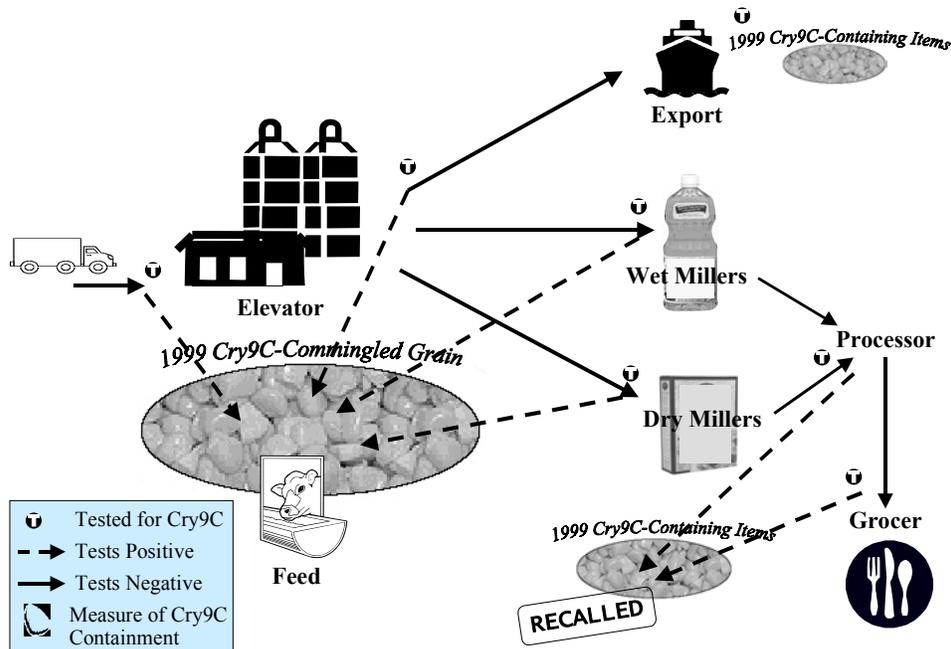


Figure 1: Capture of 1999-derived Cry9C-containing corn by the grain handling process. Cry9C-containing grain has been located in a number of shipments received in Japan, and is presumed to be the basis for several food recalls. Testing at elevators and by food processors has identified an additional volume of commingled grain, which is now being directed to animal feed and industrial uses.

It is apparent that a relatively small volume of StarLink corn grain from 1999 has become commingled in a large volume of ordinary corn. [This commingled volume also includes 2000 StarLink grain that may have been delivered to elevators prior to September 29, 2000, and Cry9C-containing grain that may have been delivered to elevators before full testing regimes were put in place.] As of March 20, 2001, of the 437 M bushels of identified commingled corn, Aventis CropScience has already facilitated the disposal (via feeding or movement to approved destinations) of 94 M bushels. Thus, 22% of the identified 1999-derived StarLink commingled grain can now be considered as eliminated from further risk calculations. The remaining 343 M bushels is currently in storage and awaiting movement to approved uses. The storage facilities involved have agreed to and have the incentive to steward this grain appropriately -- full documentation of proper use is required for settlement of claims against Aventis CropScience.

Commingled corn has come to the attention of Aventis CropScience mostly as a result of testing regimes implemented throughout the corn grain handling industry. Approximately 1.7 million test strips have been distributed to facilitate this testing to date. Only samples testing positive for Cry9C have been reported to Aventis



CropScience. No information on the corresponding volume of samples that have tested negative for Cry9C has been provided to Aventis CropScience.

The redirection of 1999-derived StarLink commingled grain to approved uses is one of the highest priorities for Aventis CropScience since doing so reduces the costs incurred to grain handlers and the company. While these volumes are large, the actual level of Cry9C inclusion is very low<sup>2</sup> due to extensive commingling.

Aventis CropScience expects to continue to provide test strips to assist the grain handling industry in the "inbound" identification of Cry9C-containing corn delivered by farmers. Only when positive tests are no longer being reported, would a change to this policy be contemplated. Thus, it is expected that the current level of vigilance will be continued and corn-testing positive for Cry9C will continue to be directed to animal feed and industrial uses. The testing program ensures that Cry9C-containing corn will be directed expeditiously to feed uses without future entry into food or mixed-use elevators.

Conclusion: Small volumes of Cry9C-containing corn from the 1999 harvest have become commingled with large volumes of ordinary corn. The dilution effect means that the actual levels of Cry9C in such volumes are very low. 22% of the corn identified to date has already been eliminated and does not need to be considered in further risk assessments. Storage facilities are expected to steward this grain well since settlement of claims against Aventis CropScience is dependent on full documentation of proper use. Although it is impossible to determine the amount of commingled Cry9C-containing corn that may yet be discovered, the diligence of the grain industry in testing indicates that any such additional volumes of corn can be accommodated by the existing process and eliminated from concern over the coming months.

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<sup>2</sup> No estimate has been made as to the average level of Cry9C in such volumes. These volumes are simply being redirected to approved animal feed and industrial use.



### 2000 StarLink Harvest

In 2000, StarLink corn was planted on ~350,000 acres in USA. This acreage is estimated to correspond to a theoretical harvest of [350,000 acres x 150 bushels/acre =] some 52.5 M bushels of StarLink grain.

Grain grown from StarLink seed: As of April 10, 2001, via direct communication with 3291 StarLink growers, Aventis CropScience estimated grain grown from StarLink seed at 49.1 M bushels. [This compares well to the anticipated harvest of 52.5M bushels.] Some of this volume moved off-farm prior to September 29, 2000, leaving 42.7 M bushels on-farm (see below). In addition, StarLink growers reported 23.1 M bushels of corn had been harvested from buffer<sup>3</sup> fields on their land. This grain was commingled with another 6.5 M bushels of ordinary corn for a total volume of 72.3 M bushels. This volume of grain and especially those amounts grown from StarLink seed, represents the highest potential concentration of Cry9C protein and as such has been assigned the highest priority for disposal. As of April 10, 2001, 37 M bushels of this corn had been, or is in the process of being, fed on farm or moved to USDA approved destinations. Thus, 50% of this grain can now be considered as eliminated from further risk calculations.

Grain grown during 2000 containing Cry9C from other sources: Lower concentrations of Cry9C can be attributed to two additional sources. (1) Some corn hybrids grown in 2000 appear to have contained low levels of Cry9C. 502 growers of these hybrids have been identified to date. (2) In addition, some buffer acres for StarLink fields have been found to lie on land belonging to neighbors of StarLink growers. Some 2079<sup>4</sup> such neighbors have been identified to date. Taken together, these sources are associated with 20.8 M bushels of commingled corn which is expected to represent a low concentration of Cry9C protein. Direction of this corn to approved uses is ongoing but is assigned a lower priority for disposal reflecting the low concentration of Cry9C. To date, 32% of this grain had been, or is in the process of being, fed on farm or moved to USDA approved destinations.

The SES Program has brought all this corn under containment (Figure 2). Option #1 of the program allows for feeding of Cry9C-containing corn on farm. The total of StarLink grain grown from seed and other sources of Cry9C-containing corn being managed under this portion of the program is 26.07 M bushels. Similarly, the total volume of Cry9C-containing corn under supervised marketing (Option #2 or Option #3) is 79.3 M bushels. The SES Program is thus controlling the utilization of some 105.37 M bushels of corn from all sources.

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<sup>3</sup> Buffer fields are defined as those fields within 660 feet of StarLink planted areas. Corn harvested from these fields must be directed to animal feed and industrial uses but is expected to contain much lower levels of Cry9C reflecting the increasing distance from StarLink pollen sources.

<sup>4</sup> On-farm corn volumes are being verified by Agricultural Information Technologies LLC (AIT). As a part of this contract, AIT professionals are also verifying neighbor information. As a result of these efforts, the accuracy of the number of neighbors affected should increase. In the meantime, any Cry9C-containing grain from these neighbors will be caught by testing regimes at elevators and will be included in commingled grain reports.

### SES Program (All 2000 Corn)

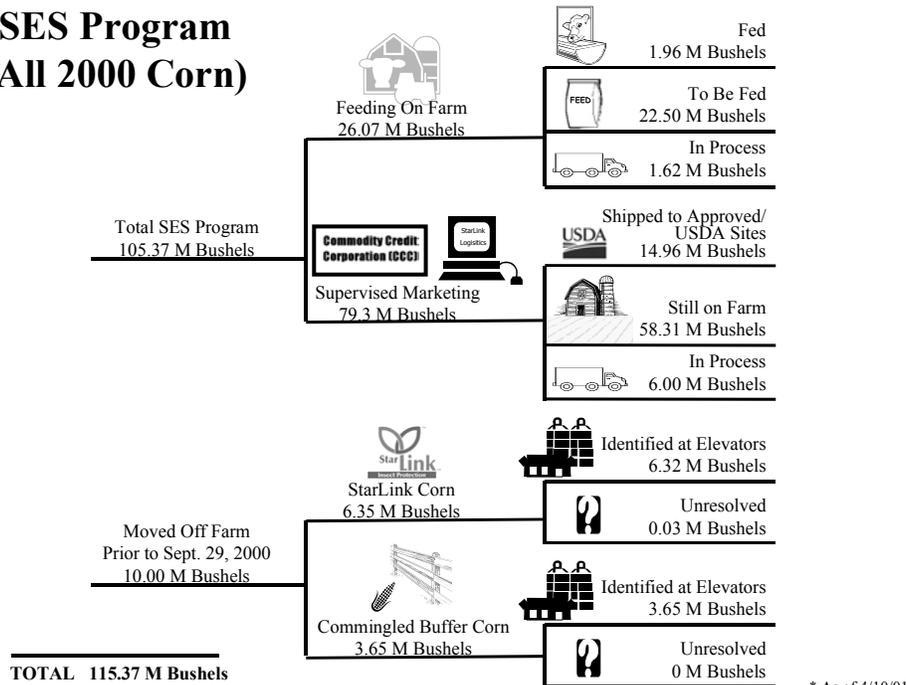


Figure 2. Disposition of all corn within the SES Program.

Grain grown from StarLink seed moved off-farm prior to September 29, 2000: Of the 49.1 M bushels of StarLink grain reported above, 6.35 M bushels reportedly left the farm prior to the implementation of the StarLink Enhanced Stewardship (SES) Program. This material has been tracked to: (a) feed and industrial use elevators -- 3.82 M bushels; (b) mixed use or transshipping elevators -- 2.50 M bushels. Aventis CropScience alerted the mixed use elevators of the need to direct Cry9C-containing grain to approved uses and is verifying that the appropriate disposition of grain occurred. As of April 10, 2001, only 30 K bushels of the off-farm grain could not be traced. An additional volume of 3.65 M bushels of commingled buffer corn has also been reported to have escaped the SES Program. It is anticipated that this volume of grain has been captured elsewhere in the food chain as a part of the commingled corn volumes reported earlier. Accordingly, Aventis CropScience has reported to the media that 99% of the grain grown from StarLink seed has been contained within the SES Program.

Thus, Aventis CropScience has now succeeded in bringing a total of 115.37 M bushels of Cry9C-containing corn produced in 2000 from all sources under its containment program.

### 2000 StarLink Grain

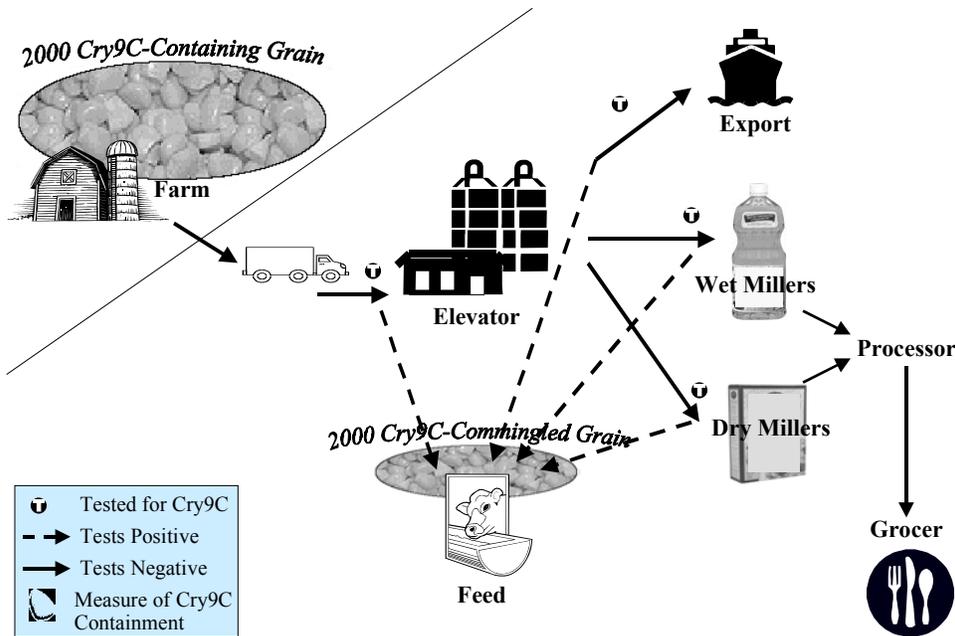


Figure 3: Capture of 2000-derived Cry9C-containing corn by the grain handling process. The largest volumes of Cry9C-containing grain have been contained on-farm. Testing at elevators and by food millers has identified an additional volume of commingled grain, which is now being directed to animal feed uses.

Figure 3 indicates the capture of 2000-derived Cry9C-containing grain by the grain handling process.

Conclusions: The highest concentration of Cry9C can be found in corn harvested from StarLink fields. The financial incentive to farmers is effective in drawing the full volume of this grain into the Aventis CropScience database. To date, 50% of this grain has already been eliminated from further risk calculations. While 13% of the corn grown (that may contain Cry9C) during 2000 had already left the farm before the SES Program began, all but a very small portion of this (30 K bushels) was directed initially or subsequently to animal feed and industrial uses. The outstanding amount has likely been captured elsewhere in the food chain as a part of the commingled corn volumes reported earlier. Cry9C-containing corn can also be attributed to other corn hybrids and fields neighboring StarLink production. This grain contains relatively low levels of Cry9C. Approximately 32% of this grain have already been eliminated from further risk calculations. Collectively, all 2000 sources of Cry9C have now been well contained within the SES Program and represent a minimal level of further concern.

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2001 Crop Season

Aventis CropScience has voluntarily withdrawn the registration for StarLink corn to provide further assurance that Cry9C-containing corn will not be planted or grown in the future.

**2001 StarLink Seed Inventory:** Aventis CropScience made it clear in the fall of 2000 that no further seed sales would occur. Seed partners have now been contacted and the destruction of their seed stocks (including any outstanding 2000 seed) is proceeding. In total, the 2001 seed inventory consisted of 27057 units<sup>5</sup> of seed. Of this inventory, 9490 units of seed were untreated with chemicals and to date, feeding to livestock has eliminated 80%. The remaining inventory, because of seed treatment, was not suitable for animal use and is being destroyed by incineration under the supervision of a third party (Mayer Seed). The objective is to have this material completely destroyed by May 1, 2001.

**2001 Volunteer Corn:** Volunteer corn from 2000 StarLink production or buffer areas has been discussed in the industry. The National Corn Growers Association has publicized the need for management of this possibility (Appendix 2). It is impossible to estimate likely levels of volunteer corn since farming practices significantly influence the extent of the issue. In the event individual growers do not exercise good volunteer corn management practices, it is anticipated that inbound testing of corn grain from the 2001 harvest at elevators would identify any significant levels of Cry9C-containing corn.

**2001 Corn Seed:** The American Seed Trade Association, the National Corn Growers Association and others have stressed that farmers should purchase only corn seed that has been tested for the presence of Cry9C. Aventis CropScience has assisted seed companies with these efforts and has supplied some 80 thousand strip tests for this purpose. USDA recently announced a special program for small seed companies to buy-back and destroy seed testing positive for Cry9C. Large seed companies have already agreed to check their seed and destroy Cry9C-containing material. Licensees of Aventis CropScience have been advised of their obligation to destroy Cry9C-containing seed. Aventis CropScience is paying for this destruction. Thus, it can be anticipated that the corn seed for use in 2001 will be largely free of Cry9C.

**Field Trials:** Aventis CropScience has stopped all further commercial and breeding development of StarLink corn globally until a full assessment of the product is completed. Field trials with Cry9C-containing corn that were scheduled for fall 2000/spring 2001 in Hawaii and Puerto Rico were destroyed before pollination occurred. Aventis CropScience trait managers, upon instruction from corporate management, are actively notifying all seed companies who have Cry9C seed to destroy all such material. Aventis CropScience is providing technical advice and support to seed companies in an effort to ensure global removal of material containing Cry9C.

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<sup>5</sup> Each unit is one bag of seed consisting of ~80,000 seeds and weighing ~54 pounds. One unit of seed is sufficient to plant 2-3 acres depending on seeding rate.

Figure 4 indicates the action corresponding to each potential "new" source of Cry9C.

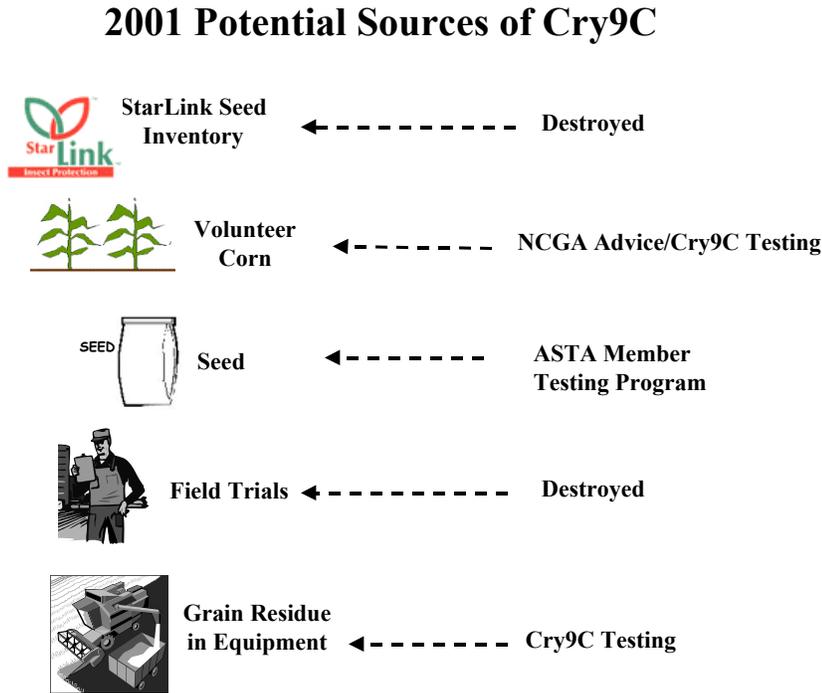


Figure 4: Response actions for each potential "new" source of Cry9C  
 Each potential new source of Cry9C has been addressed by direct action.

Grain Residue in Equipment: Small quantities of StarLink or Cry9C-containing corn grain may remain in farm equipment, storage containers, or transportation vehicles after use. While these quantities are small, they represent a potential future source of Cry9C. The sensitivity of testing regimes at elevators is anticipated to ensure that any significant quantities of such grain commingled in larger volumes will be detected and redirected to animal feed uses.

Conclusion: StarLink seed inventory is expected to be completely destroyed by May 1, 2001. Farmers have received advice on controlling volunteer corn and any weaknesses in carrying out such management are expected to be detected by Cry9C testing of the 2001 corn harvest at elevators. Based on the testing regimes currently in place, corn seed for planting in 2001 can be expected to contain fewer than 1 seed in 2400 seeds potentially testing positive for Cry9C. Thus, the risk of "new sources" of Cry9C entering the food supply from the 2001 corn harvest is very small.

### The Evolution of the SES Process

The SES management processes have evolved since their initial implementation.

- Farmer contact was initially based upon grower lists provided by seed companies. These lists contained numerous flaws. The publicity associated with the SES program and the opportunity for farmers to benefit from participation in the program has meant that farmers have become increasingly self-identifying. A very high level of farmer cooperation has been achieved as a result. The eligibility of even non-SES participating farmers to make claims against Aventis CropScience further increases the likelihood that Aventis CropScience will have access to high quality information on the disposition of Cry9C-containing corn grain.
- Initially, farmer-derived information was used to identify grain elevators that may have received Cry9C grain. This approach was not sufficient for the grain elevators and their customers. Aventis CropScience has now supplied over 1.7 million test strips for use by this industry to identify Cry9C-containing volumes of grain and facilitate proper direction to approved uses.
- Figure 5 indicates where testing procedures are now being used<sup>6</sup>. In addition to specific questioning of growers, most elevators have implemented inbound testing before grain is accepted into an elevator. Shipments destined for export use are tested as they leave the elevator. Food processors such as wet or dry millers have implemented inbound testing to ensure their facilities receive only suitable materials. Grain which tests positive for Cry9C at any point is promptly redirected to animal feed use with or without the intervention of Aventis CropScience. Under the existing regime, repeated testing of the same grain volume is not encouraged but may occur. As part of the settlement process of claims against Aventis CropScience, claimants must commit to implementing future inbound testing.
- All parts of the grain trade are aware that Aventis CropScience has implemented a claims procedure for costs associated with the direction of Cry9C-containing corn to animal feed and industrial uses. In order to process such claims, documentation of delivery to approved uses is required. Thus all parts of the chain have an incentive to properly direct and thoroughly document their handling of material testing positive for Cry9C.

Conclusion: The financial incentives and claims settlement procedures implemented by Aventis CropScience to manage the Corn Containment Program are successfully providing all parts of the grain trade with an incentive to properly direct and thoroughly document the use of Cry9C-containing corn. The information collected as a result of this program provides confidence that all potentially important aspects are fully integrated into the current program.

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<sup>6</sup> In general, sampling methods for large volumes are dependent on moving the grain in a stream between two containers. Thus testing is effectively limited to inbound or outbound testing at elevators and can only be achieved during storage if the grain is transferred between holding containers.

### StarLink Grain Handling Process

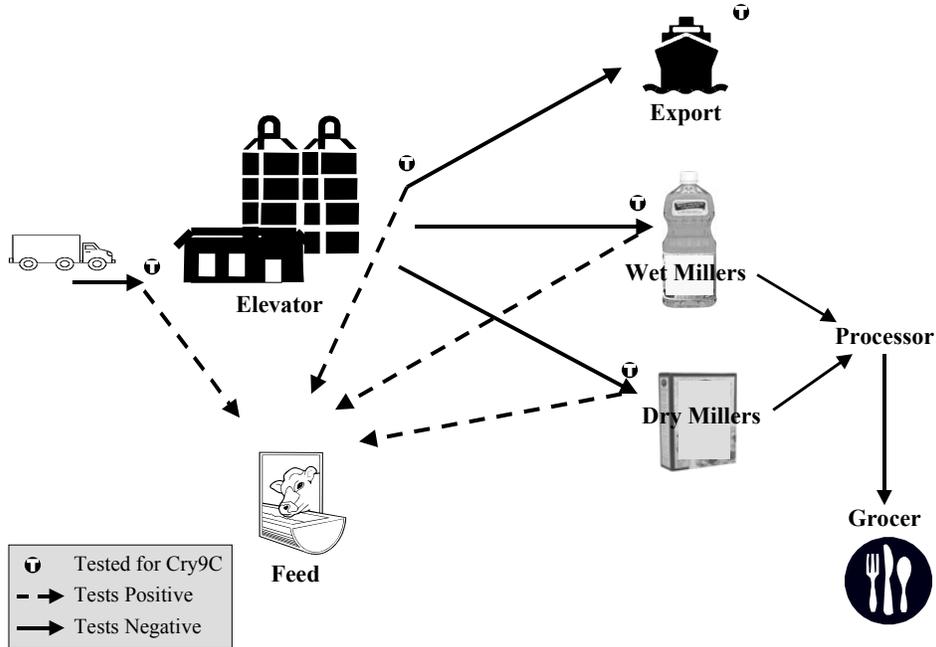


Figure 5: Role of Cry9C testing in determining the use of corn grain. Process developed by industry to ensure Cry9C-containing grain is identified and directly to animal feed or industrial uses.

Assessment of Future Risk Based Upon the Corn Containment Program

According to the information described above, 1999-derived Cry9C-containing corn has been caught either at elevators or food mills where an extensive testing regime has been implemented. Although the volumes involved are large, the actual concentration of Cry9C protein is very low reflecting a large degree of commingling. To date, 22% of identified 1999 Cry9C-containing commingled grain has been eliminated by feeding to animals or delivery to approved USDA destinations. While the final amount of Cry9C-containing corn that may yet be identified is unknown, Aventis CropScience is successfully directing this corn to approved uses. Additional volumes of corn that may yet be identified can be confidently handled under the existing program.

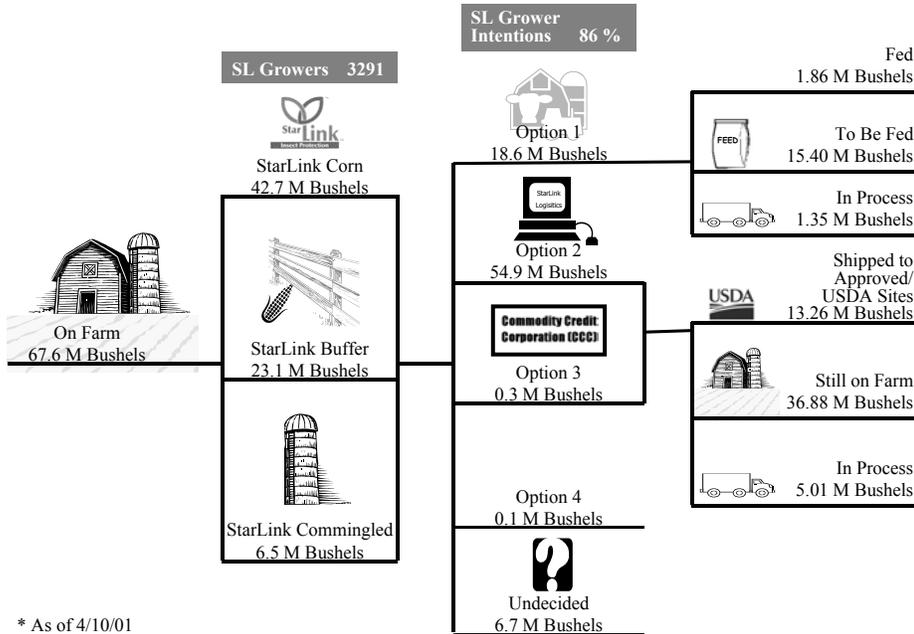
Over 99% of grain grown from StarLink seed during the 2000 season has been contained on farm and 50% of the total volume has been, or is being, eliminated by feeding to animals or delivery to USDA approved destinations. Only a very small amount (~30 K bushels) of the corn grown from StarLink seed which left the farm before the SES Program was implemented has not been traced. It is expected that this small volume has already been captured elsewhere in the food chain or is accounted for in the previously reported Cry9C-containing commingled grain volumes.

The ongoing risk from "new sources" of Cry9C has been managed through separate actions addressing the systematic destruction of StarLink seed inventory, management advice regarding volunteer corn, and verification procedures for 2001 corn seed. Thus, the risk of new sources of Cry9C entering the food supply from the 2001 corn harvest is very small.

The financial incentives and claims settlement processes implemented by Aventis CropScience have successfully provided a motivation for all parts of the grain trade to properly direct and thoroughly document the appropriate use of Cry9C-containing corn.

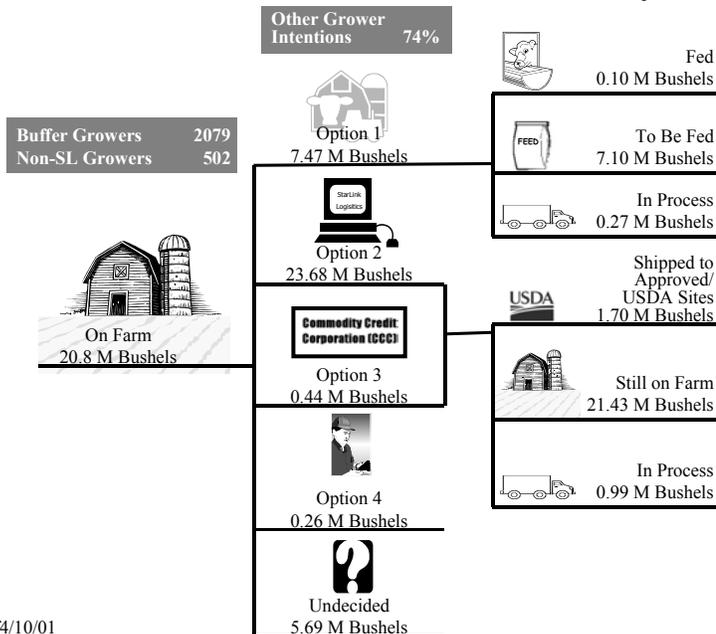
In summary, all known sources of Cry9C have now been successfully circumscribed by the SES Program, Aventis CropScience and the diligent testing efforts of the grain handlers and food millers. While the final grain volumes that may result from each source cannot be fully determined at this point, it is clear that each identification, containment and redirection element is fully functional and is achieving the desired outcome. Provided that the level of testing diligence is maintained, the likelihood of Cry9C entering human food products in the future is extremely low.

### Bushels From StarLink Corn\* (All 2000 Corn)



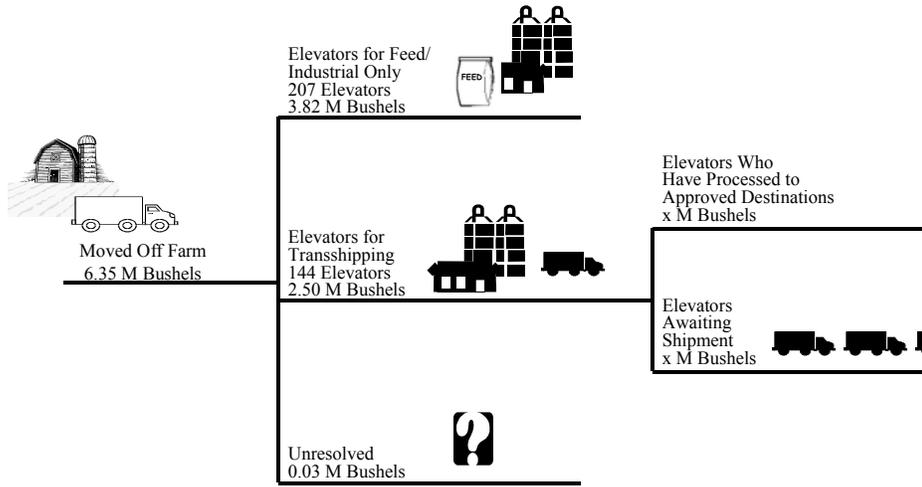
\* As of 4/10/01

### Bushels From Other Sources of Cry9C\*



\* As of 4/10/01

## Bushels From StarLink Seed Moved Off Farm Prior to 9/29/00



\* As of 4/10/01

## Appendix 2

The following note was posted recently on the website of the National Corn Growers Association.

**Corn Growers Must Make the Extra Effort to Control Volunteer StarLink (2-13-01)**

The National Corn Growers Association (NCGA) is urging growers who planted StarLink hybrids last year to make the extra effort to control possible volunteer StarLink corn in 2001. That may mean rotating to another crop or growing a herbicide-tolerant hybrid that lets you control volunteer StarLink. "The danger is volunteer StarLink corn pollinating surrounding non-StarLink corn plants, further compounding the problems of keeping StarLink out of the supply of U.S. corn," said Fred Yoder, Plain City, Ohio, farmer and chairman of the NCGA Biotech Working Group. "Rotation is the best choice," he pointed out. "In an ideal situation for 2001, you'd rotate ground planted to StarLink last year into soybeans, oats, or some other crop that will allow you to find and destroy volunteer corn. "But if you're locked into growing corn-on-corn you need to plant herbicide-tolerant hybrids that let you eliminate StarLink volunteers," Yoder stressed. The other control options are to grow either glyphosate (Roundup Ready) tolerant hybrids or imidazolinone (IMI) Clearfield tolerant hybrids and then use those herbicides to kill volunteer corn and other weeds. However, NCGA is warning farmers about the use of Roundup Ready hybrids to control StarLink volunteers. "Roundup Ready corn is not yet approved for export to the European Union and is restricted from some domestic wet-milling markets," Yoder emphasized. "Check your primary corn market before selecting this control option. "Planting glufosinate (LibertyLink) tolerant hybrids or using conventional corn herbicides on StarLink ground will not control volunteers, because StarLink contains the LibertyLink gene," he added. "Also, you'll need to check with your seed dealer to see whether the StarLink hybrids you planted last year were stacked with IMI. If they were, you can't control volunteer StarLink with an IMI hybrid." The recommendation on controlling StarLink volunteers is in addition to NCGA's recent statement encouraging growers to plant seed that has been tested for Cry9C, the StarLink protein. For more information about the National Corn Growers Association and biotechnology, visit the NCGA website at [www.ncga.com](http://www.ncga.com) <<http://www.ncga.com>>.